

Congress of the United States

Washington, DC 20515

May 17, 2004

The Honorable David M. Walker
Comptroller General
U.S. General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Walker:

We are writing to ask you to investigate the Food and Drug Administration's recent decision not to make emergency contraception available over-the-counter without a prescription. This decision went against the advice of both advisory committees that considered the application to switch emergency contraception from prescription drug status to over-the-counter status. It also conflicted with the advice of the FDA staff who reviewed the application.

There have been serious allegations that what should have been a science-based decision was influenced by inappropriate political considerations. Two of the members of one of the advisory committees who considered this application, Dr. Michael F. Greene and Dr. Alastair Wood, published an editorial in the *New England Journal of Medicine* in April in response to FDA's announcement that it was delaying its decision on whether to make Plan B available over-the-counter. In that commentary, these distinguished scientists wrote:

The recent decision by the Food and Drug Administration (FDA) to postpone a decision on the proposal to switch levonorgestrel emergency contraception (sold under the brand name Plan B) to over-the-counter status suggests that the FDA's decision-making process is being influenced by political considerations. The data overwhelmingly demonstrate that emergency contraception is safe and effective when available without a prescription. Moreover, the evidence shows that the availability of emergency contraception does not result in a change in the usual behavior or contraceptive practices of the women who are its potential users. A treatment for any other condition, from hangnail to headache to heart disease, with a similar record of safety and efficacy would be approved quickly.¹

The editorial also said that allowing political interference with what should be a science-based decision could undermine public confidence in the drug approval process.

This concern was echoed by Vivian M. Dickerson, President of the American College of Obstetricians and Gynecologists, who said: "[The FDA's] action is a tragedy for American women, and a dark stain on the reputation of an evidence-based agency like the FDA."²

¹ Jeffrey M. Drazen, M.D., Michael F. Greene, M.D., and Alastair J.J. Wood, M.D., *The FDA, Politics, and Plan B*, *New England Journal of Medicine* (Apr. 8, 2004).

² *FDA: Plan B Sales Rejected against Advice*, *Washington Post* (May 8, 2004).

Even FDA officials admit that this was an irregular decision. According to press accounts, Dr. Steven Galson, the Acting director of the FDA's Center for Drug Evaluation and Research, and the person who signed the "not-approvable" letter, said, "I am not trying to convey this decision as being common or usual."³ Former FDA officials "could not remember another instance in which Dr. Galson . . . or any of his predecessors had overruled both an advisory committee and staff recommendations."⁴

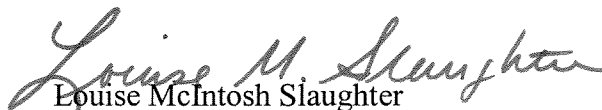
The integrity of the FDA drug approval system, and of public confidence in the safety and efficacy of the drugs FDA approves, depends on these decisions being free from political influence. Therefore, we are asking that GAO investigate whether FDA's decision not to approve Barr Lab's application to make Plan B available over-the-counter was affected by political considerations. As part of your investigation we ask that you interview all those who were involved in the review of the application and in the decision making process. We also ask that you review any and all communications between any employee of the White House and/or the Department of Health and Human Services and any employee of FDA regarding this application.

If you have any questions about this request, please contact Sarah Despres of the Minority Staff of the Government Reform Committee at (202) 225-5420. We look forward to meeting to further elaborate on the specifics of this request.


Sincerely,



Henry A. Waxman
Ranking Minority Member
Committee on Government Reform



Louise McIntosh Slaughter
Member of Congress



Carolyn B. Maloney
Member of Congress



Joseph Crowley
Member of Congress



Barbara Lee
Member of Congress



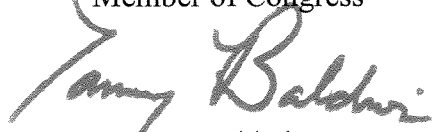
Lloyd Doggett
Member of Congress

³ *Morning-After-Pill Ruling Defies Norm*, New York Times (May 8, 2004).

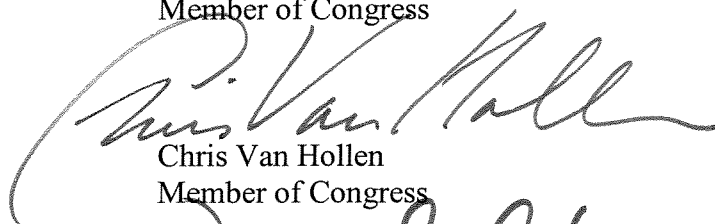
⁴ *Id.*



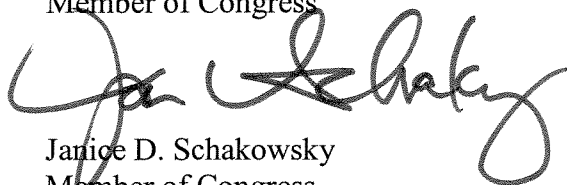
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Tammy Baldwin
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Chris Van Hollen
Member of Congress



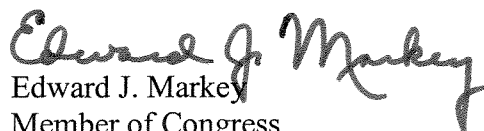
Janice D. Schakowsky
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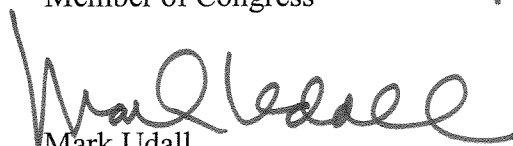
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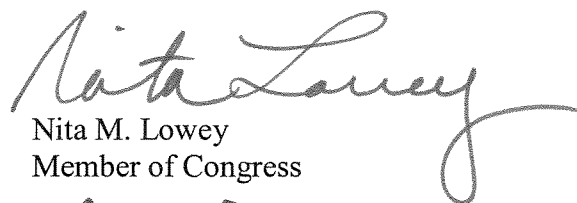
James P. Moran
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Edward J. Markey
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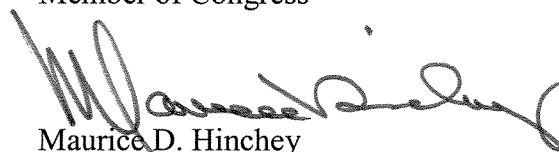
Mark Udall
Member of Congress



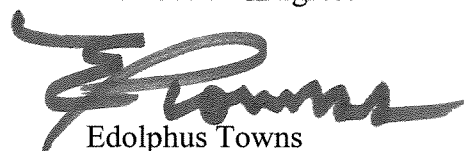
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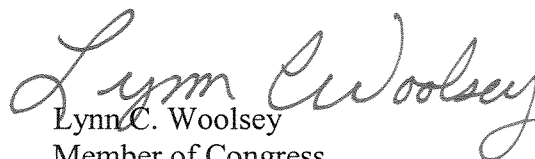
Susan A. Davis
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Michael M. Honda
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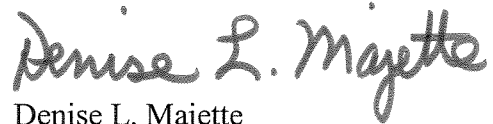
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Diane E. Watson
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